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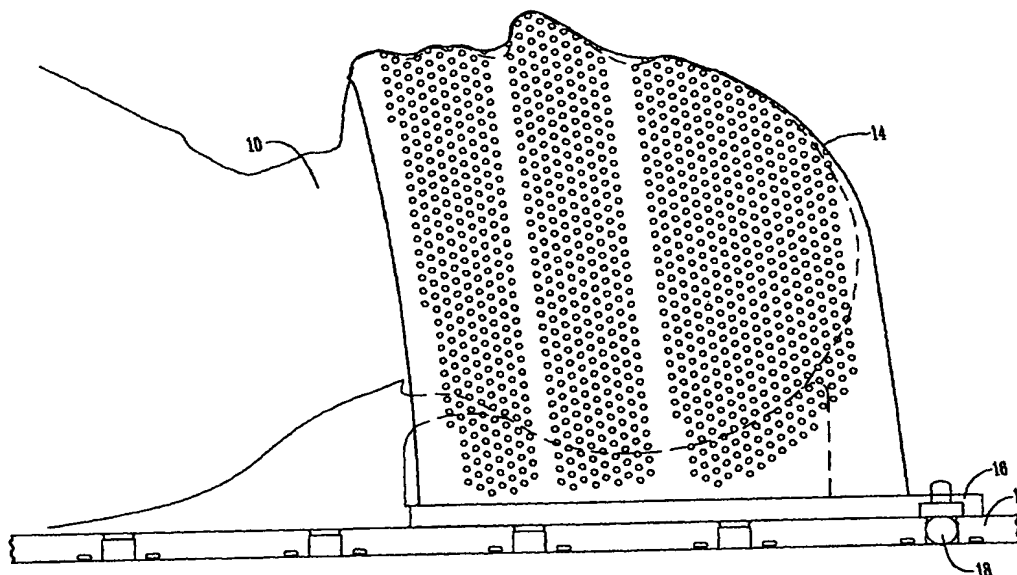
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(54) Title: **REINFORCED THERMOPLASTIC PATIENT RESTRAINTS FOR RADIATION THERAPY**



(57) Abstract: A patient restraint member is provided for medical procedures, such as radiation therapy. The restraint member is formed from a sheet of thermoplastic material that can be softened upon heating so as to be formable into a shape corresponding to a patient's body part to be restrained and setting upon cooling to retain the shape. The sheet includes spaced apart groups of perforations which minimize shrinkage during the formation process. The sheet also includes solid bands extending between the groups of perforation to provide rigidity and strength to the formed sheet.

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*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

## REINFORCED THERMOPLASTIC PATIENT RESTRAINTS FOR RADIATION THERAPY

## 5 BACKGROUND OF THE INVENTION

Thermoplastic sheets are well known for use in the field of radiation therapy treatment, including Intensity Modulated Radiation Therapy (IMRT). Typically, such thermoplastic sheets are heated and then formed to a shape corresponding to the body part to be restrained, such as a mask for restraining a patient's head. The sheet is mounted on a  
10 frame which can be secured to a treatment table to facilitate proper positioning of the patient on the table for radiation treatment.

The prior art thermoplastic sheets are solid sheets or perforated sheets. Solid thermoplastic sheets require much higher forces to form, retain much more heat and tend to have excess shrinkage when formed to the body shape, all of which leads to patient  
15 discomfort. The perforations serve to reduce the force necessary to form, minimize the heat transferred to the patient, and minimize shrinkage of the thermoplastic material. When the sheet is formed into a facemask, the holes permit a patient to see and breathe through the sheet, and thereby minimize or eliminate claustrophobic feelings. The holes can be punched into the sheet, or formed when the sheet is made in an injection molding  
20 process. However, totally perforated sheets do not offer the necessary rigidity which is present in a solid or non-perforated sheet.

Accordingly, a primary objective of the present invention is the provision of an improved thermoplastic sheet for use in medical procedures, including IMRT.

Another objective of the present invention is the provision of an improved  
25 thermoplastic sheet having perforations and non-perforated reinforcing bands.

Further objective of the present invention is the provision of an improved perforated thermoplastic sheet with enhanced rigidity.

Another objective of the present invention is the provision of an improved thermoplastic sheet which is sufficiently rigid, and which avoids excess shrinkage.

30 A further objective of the present invention is the provision of an improved thermoplastic sheet, which is comfortable when used on a patient for medical procedures.

These and other objectives will become apparent from the following invention.

## BRIEF SUMMARY OF THE INVENTION

The improved thermoplastic sheet of the present invention is intended for use as a patient restraint member in medical procedures such as radiation therapy treatment, including IMRT. The sheet may take various forms and shapes to restrain various body parts, including the head, neck, breasts, and hips/pelvic area. The sheet includes a plurality of groups of perforations to increase patient comfort, with non-perforated bands extending between the groups of perforation to provide enhanced rigidity. The perforations also minimize shrinkage of the sheet when it is heated, formed, and cooled into a set shape corresponding to the body part to be restrained. The perimeter edge of the sheet is free from perforations. The solid bands extend inwardly from the perimeter edge of the sheet. The bands may extend completely or partially across the sheet. The solid bands are placed in strategic areas to provide increased rigidity while the perforations minimize shrinkage. The perforations may be punched or formed during injection molding.

## BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a side elevation view of a thermoplastic sheet formed into a mask for restraining a patient's head and mounted onto a radiation treatment table.

Figures 2-5 are each a top plan view of a sheet adapted to be formed into a head restraint, and showing various alternative embodiments of the perforation groupings and solid reinforcing bands, according to the present invention.

Figure 6 is a top plan view of a thermoplastic sheet adapted to be formed into a head and shoulder restraint with the perforations and reinforcing bands of the present invention.

Figure 7 is a top plan of a thermoplastic sheet adapted to be formed into a breast restraint with the perforations and reinforcing band of the present invention.

Figure 8 is a top plan view of a thermoplastic sheet adapted to be formed into a hip/pelvic restraint and having the perforations and reinforcing bands of the present invention.

## DETAILED DESCRIPTION OF THE INVENTION

In Figure 1 a patient 10 as shown on a treatment table 12 in preparation for radiation therapy on his/her head. The patient's head is restrained by a thermoplastic mask 14, which has been formed to fit the patient's head. The mask 14 is mounted on a frame 16, which is adapted to be secured to the treatment table 12 in any convenient manner. For example, the table 12 may include a plurality of indexing notches adapted to receive an indexing member 18 extending from the frame 16, as described in the U.S. patent 6,161,237.

The mask 14 is formed from one of the thermoplastic sheets 20A-20D shown in figures 2-5, respectively. Each sheet 20 includes spaced apart groups of perforations or holes 22 extending through, or partially through, the sheets 20A-20D. The spacing between the groups of the holes define solid bands 24 which increase the rigidity of the sheets 20A-20D, and thus the mask 14. The holes 22 minimize shrinkage of the sheets during the mask formation process. Each of the sheets 20A-D has a non-perforated perimeter edge 26 for securement of the sheet to the U-shaped frame 16. Alternatively, the groups of holes 22 may extend to the edge of the sheet 20A-D, which facilitates bonding of the sheet 20A-D to the frame 16, for example using adhesives or heat. The non-perforated bands 24 extend inwardly from the perimeter edge 26 of the sheets 20A-D. Some bands 24 may extend completely across the sheets 20a-d while other bands 24 extend partially across the sheets. Also, the bands 24 may extend perpendicularly to the opposite side edges, top edge, or bottom edge, or angularly thereto in a non-perpendicular orientation. As seen in Figure 5, some of the bands may criss-cross the sheet 20D. The holes 22 may be formed by punching or during an injection process used to make the sheets 20A-D.

Figure 6 shows another sheet 28 adapted to be formed for restraining the head and shoulders of a patient. The holes 22 in the sheet 28 minimize shrinkage, while the solid bands 24 provide increased rigidity for the sheet 28 after it is heated, formed, and cooled to the set shape.

Figure 7 shows another embodiment of the present invention where in a sheet 30 having holes 22 and a solid band 24 is adapted for formation and use in restraining the upper torso of a patient, for example, in breast radiation treatment. Similarly, Figure 8 shows a thermoplastic sheet 32 with holes 22 and solid bands 24 according to the present invention. The sheet 32 is adapted to be formed and used as a hip/pelvic restraint. The

enlarged holes 34 along the edges of the sheets 30 and 32 are used for attaching the sheets 30, 32 to a frame (not shown) which is then mounted to the treatment table.

Whereas the invention has been shown and described in connection with the preferred embodiment thereof, it will be understood that any modifications, substitutions, and additions may be made which are within the intended broad scope of the following claims. From the foregoing, it can be seen that the present invention accomplishes at least all of the stated objectives.

What is claimed is:

1. A patient restraint member for use in medical procedures, comprising:  
a sheet of thermoplastic material that can be softened upon heating so as to be formable  
into a shape corresponding to a patient's body part to be restrained and setting upon  
cooling to retain the shape;  
spaced apart groups of perforations in the sheets; and  
solid bands extending between the groups of perforations.
2. The patient restraint member of claim 1 wherein the sheet has a perimeter edge and  
the bands extend inwardly from the edge.
3. The patient restraint member of claim 2 wherein the bands intersect at a location  
spaced inwardly from the edge.
4. The patient restraint member of claim 2 wherein the bands extend perpendicular to  
the edge.
5. The patient restraint member of claim 2 wherein the bands extend in a non-  
perpendicular angle from the edge.
6. The patient restraint member of claim 2 wherein the bands extend completely  
across the sheet.
7. The patient restraint member of claim 1 wherein the sheet has a perimeter edge  
without perforations.
8. The patient restraint member of claim 1 wherein the solid bands extend across the  
sheet.
9. The patient restraint member of claim 1 wherein the spaces between the groups of  
perforations define the solid bands.

10. A patient restraint member for use in medical procedures, comprising:  
a partially perforated sheet of thermoplastic material that can be softened upon heating so  
as to be formable into a shape corresponding to a patient's body part to be  
restrained and setting upon cooling to retain the shape;  
5 at least one non-perforated band extending at least partially across the sheet to enhance  
rigidity of the sheet.

11. The patient restraint member of claim 10 wherein the sheet has a perimeter edge  
and the band extends perpendicular to the edge.

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12. The patient restraint member of claim 10 wherein the sheet has a perimeter edge  
and the band extends at a non-perpendicular angle to the edge.

13. The patient restraint member of claim 10 wherein the sheet has opposite side edges  
15 and opposite top and bottom edges, and the edges are non-perforated.

14. The patient restraint member of claim 13 wherein the band extends between the  
opposite side edges.

20 15. The patient restraint member of claim 10 wherein the band extends completely  
across the sheet.

16. The patient restraint member of claim 10 the sheet has a perimeter edge and further  
comprising a plurality of non-perforated bands extending inwardly from the perimeter  
25 edge.

17. The patient restraint member of claim 10 with the bands criss-cross the sheet.



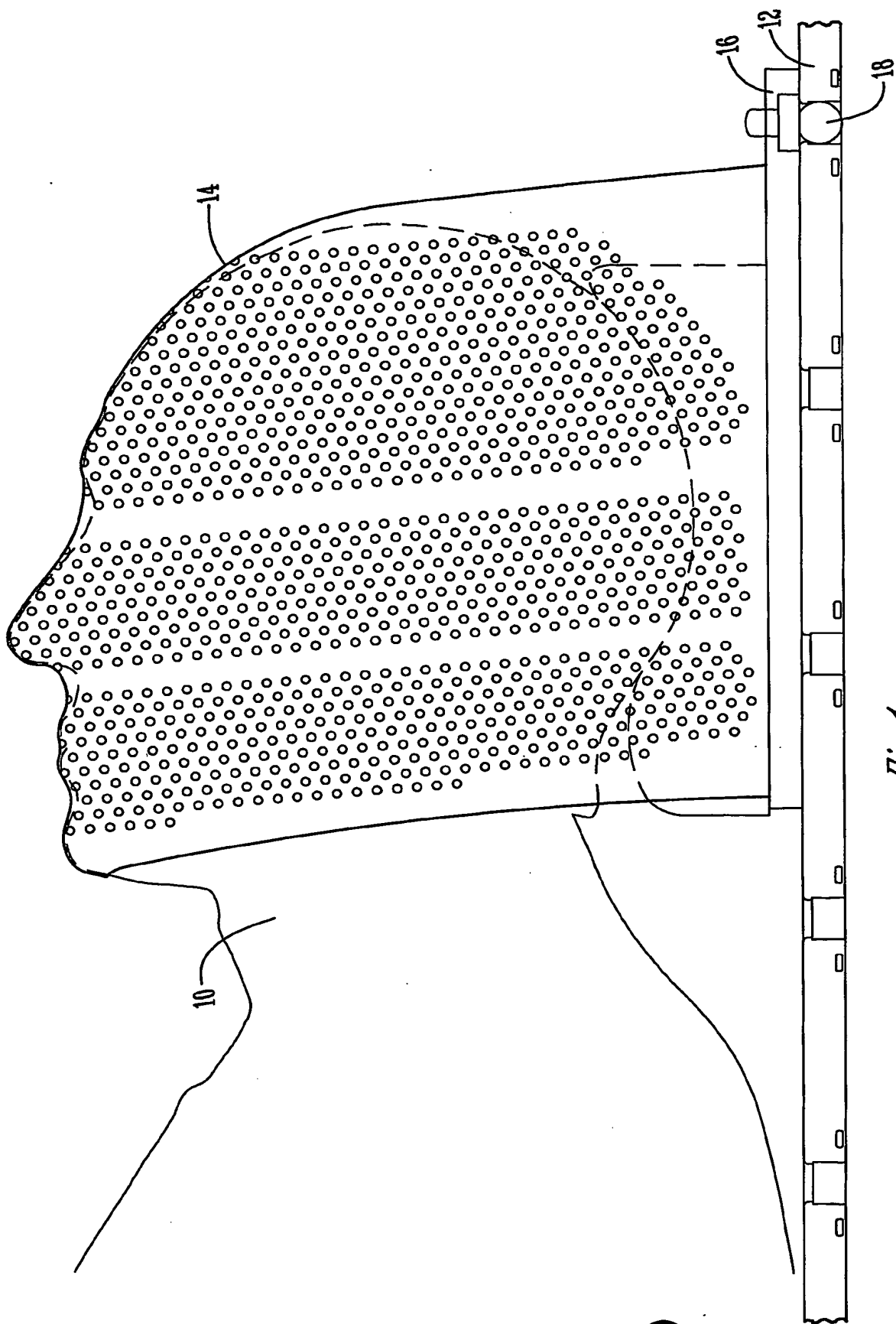
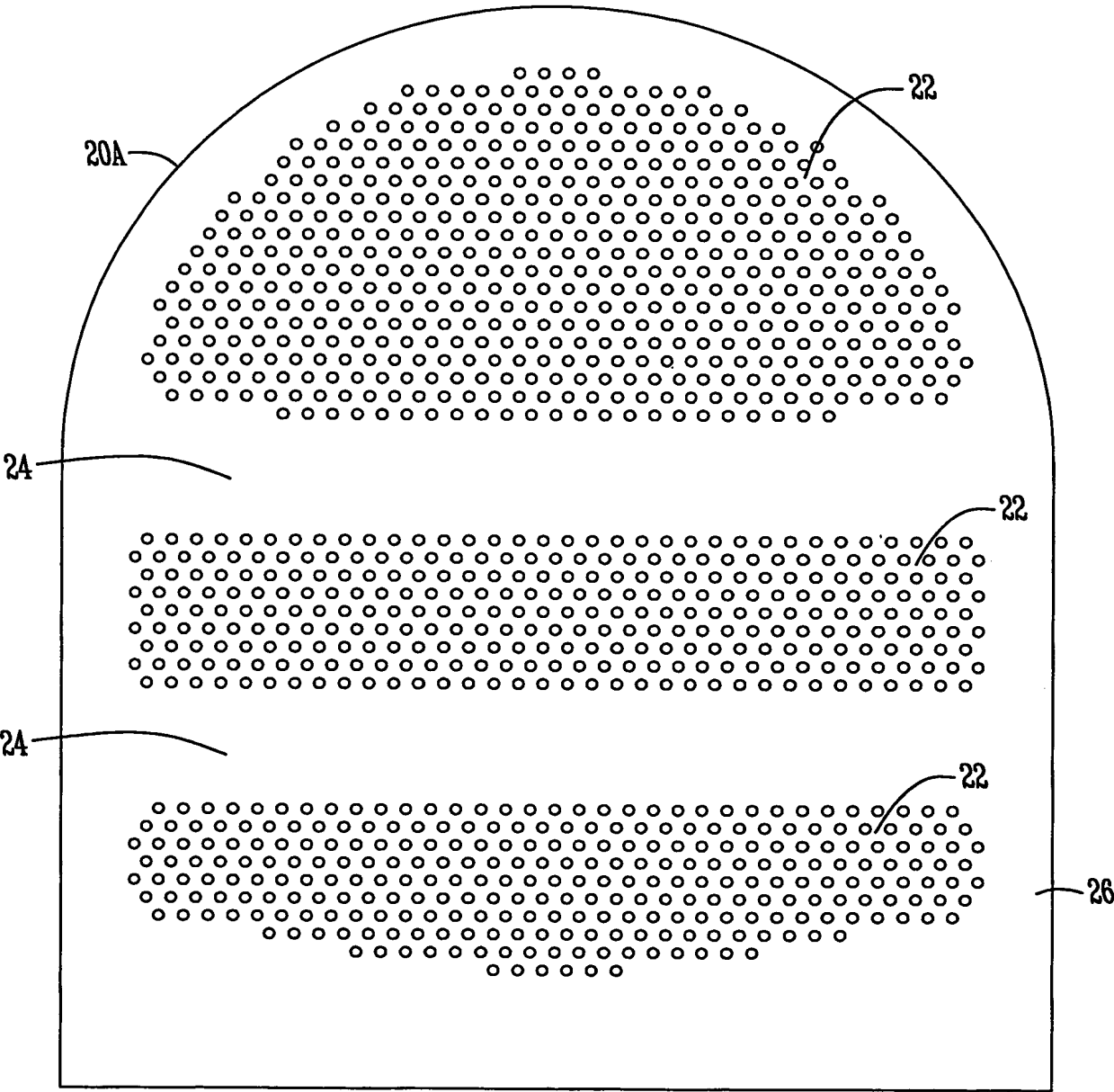
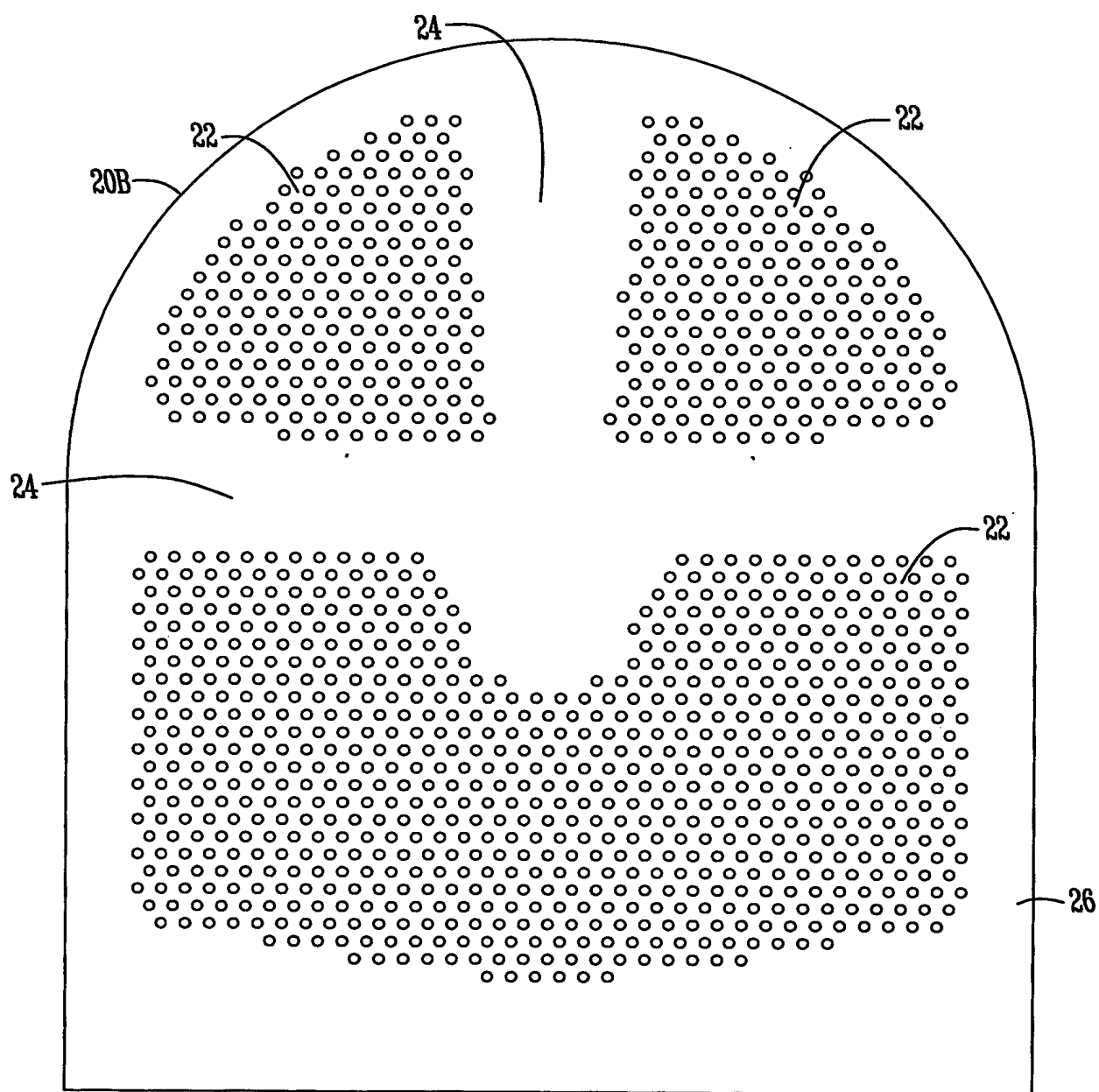
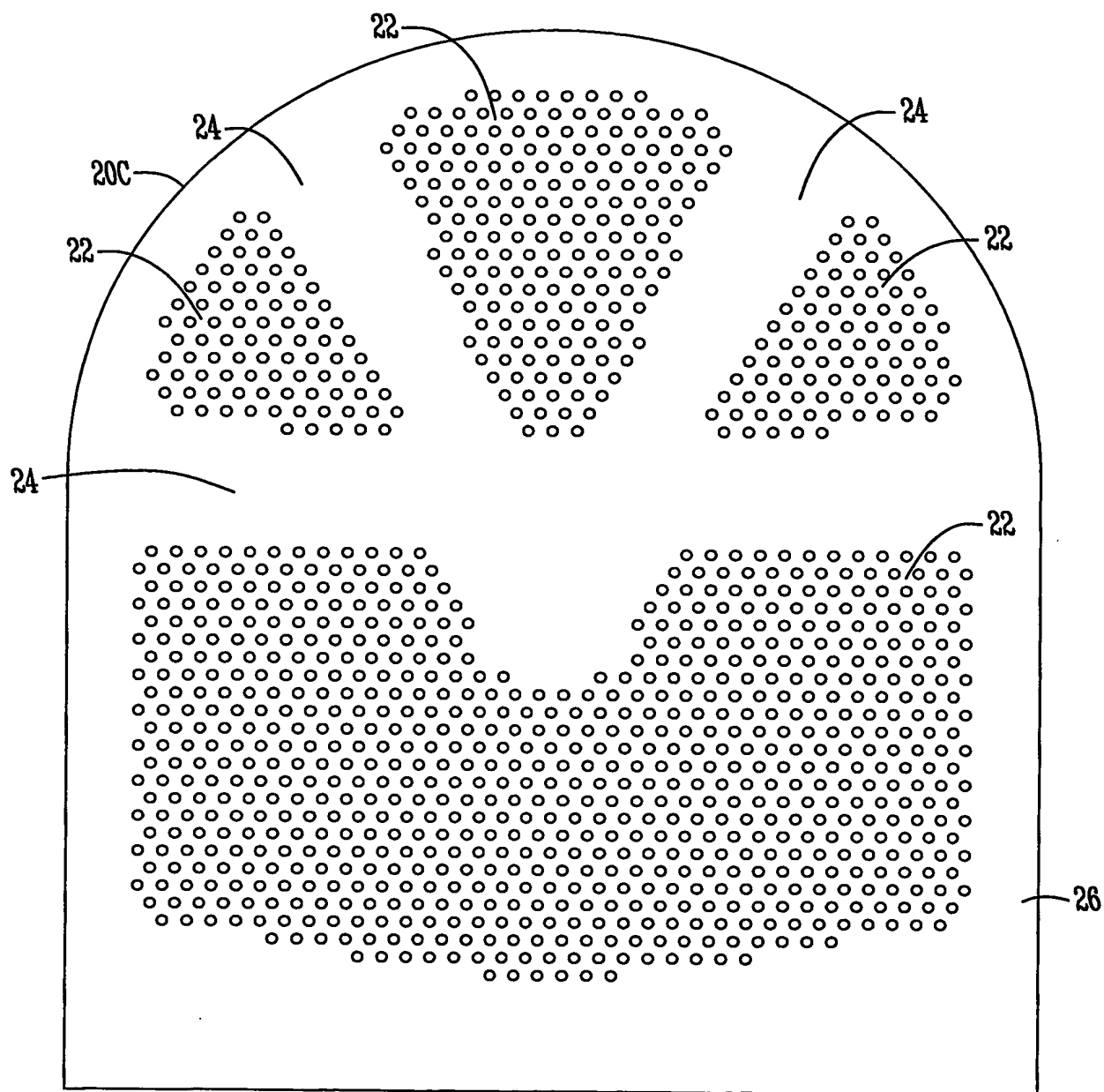


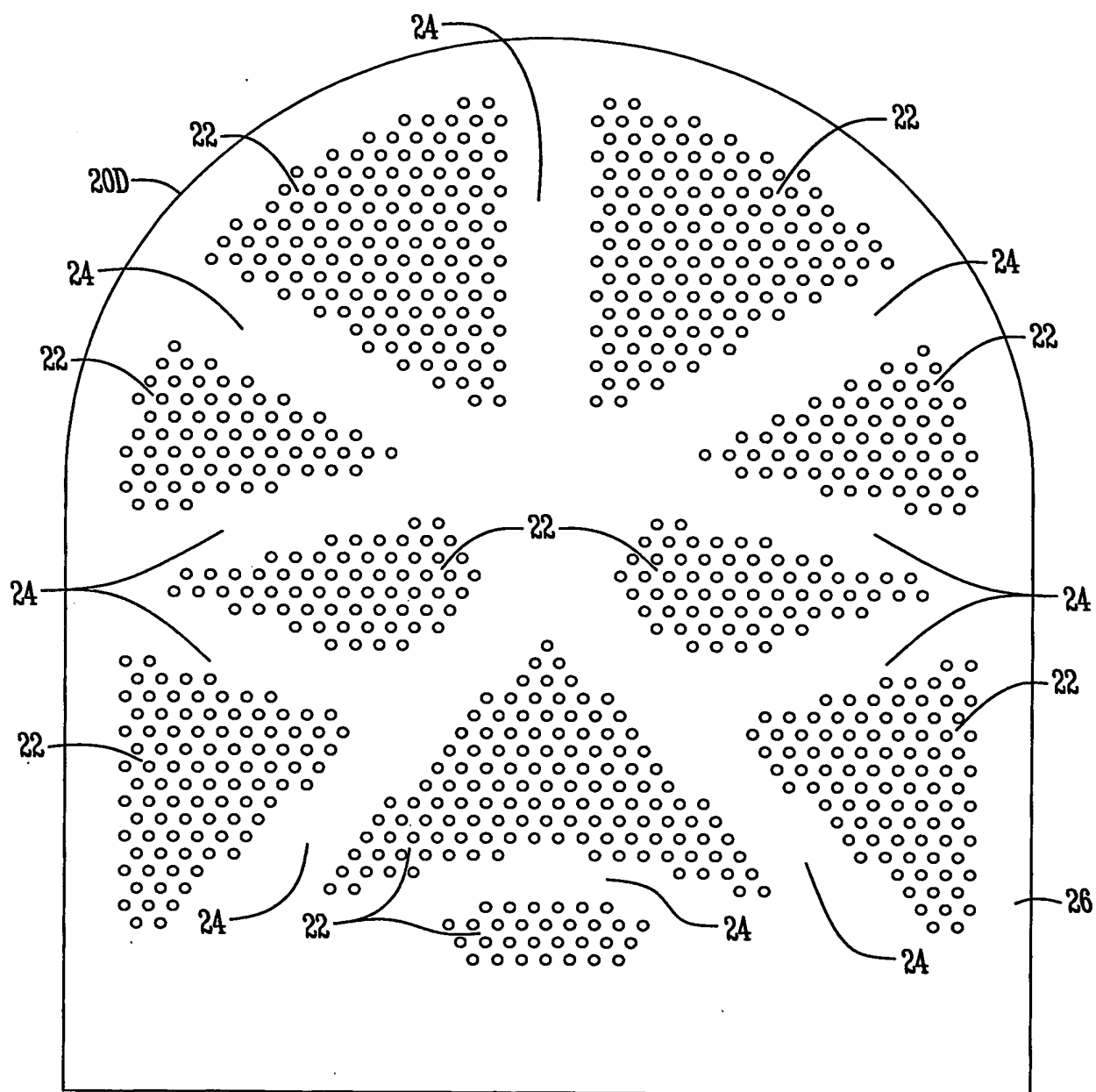
Fig. 1

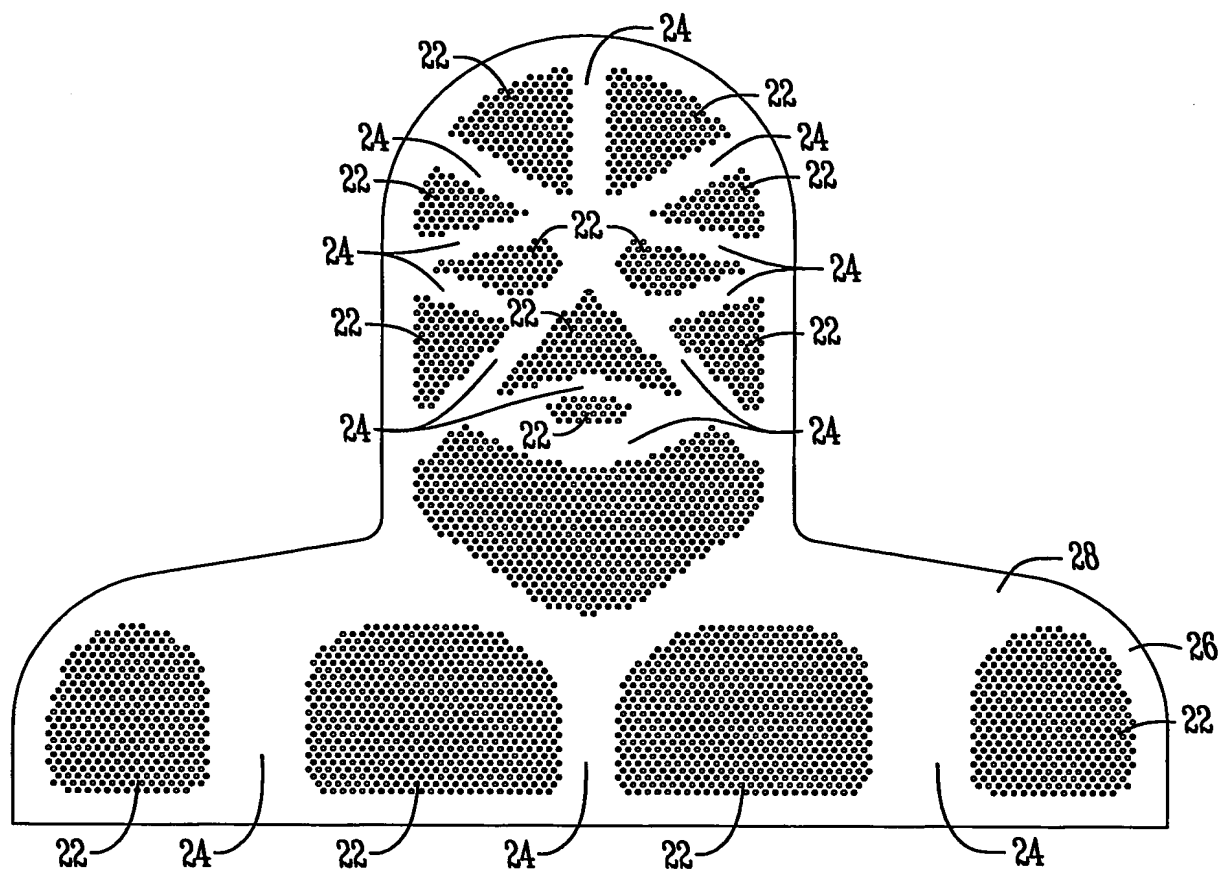


*Fig. 2*

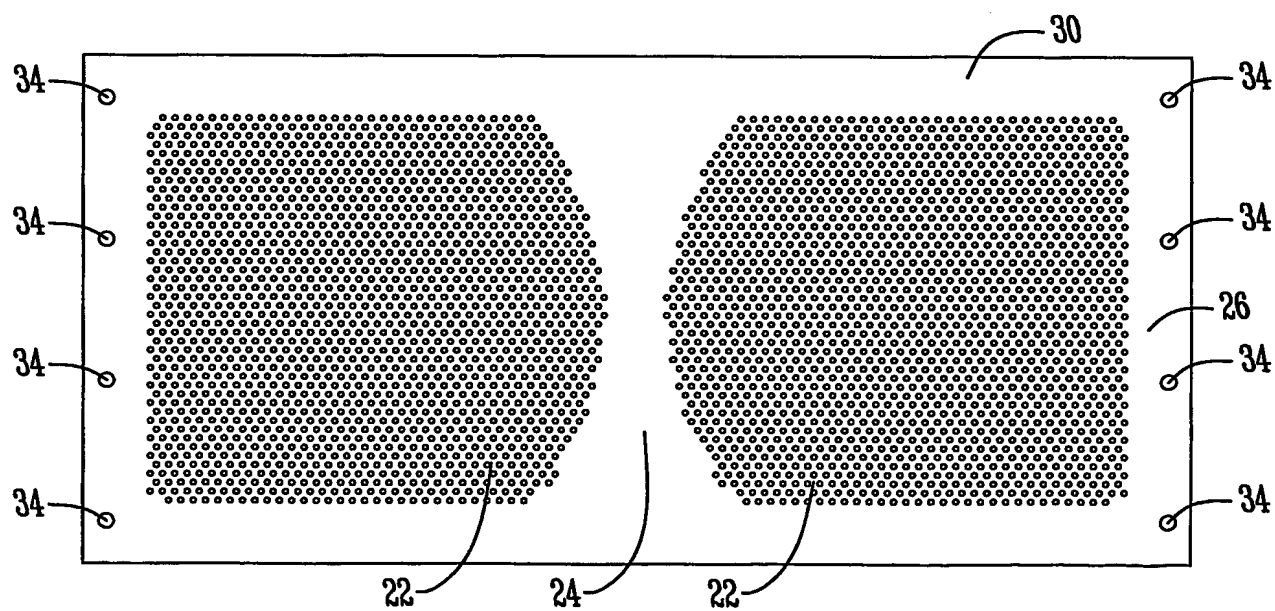
*Fig. 3*

*Fig. 4*

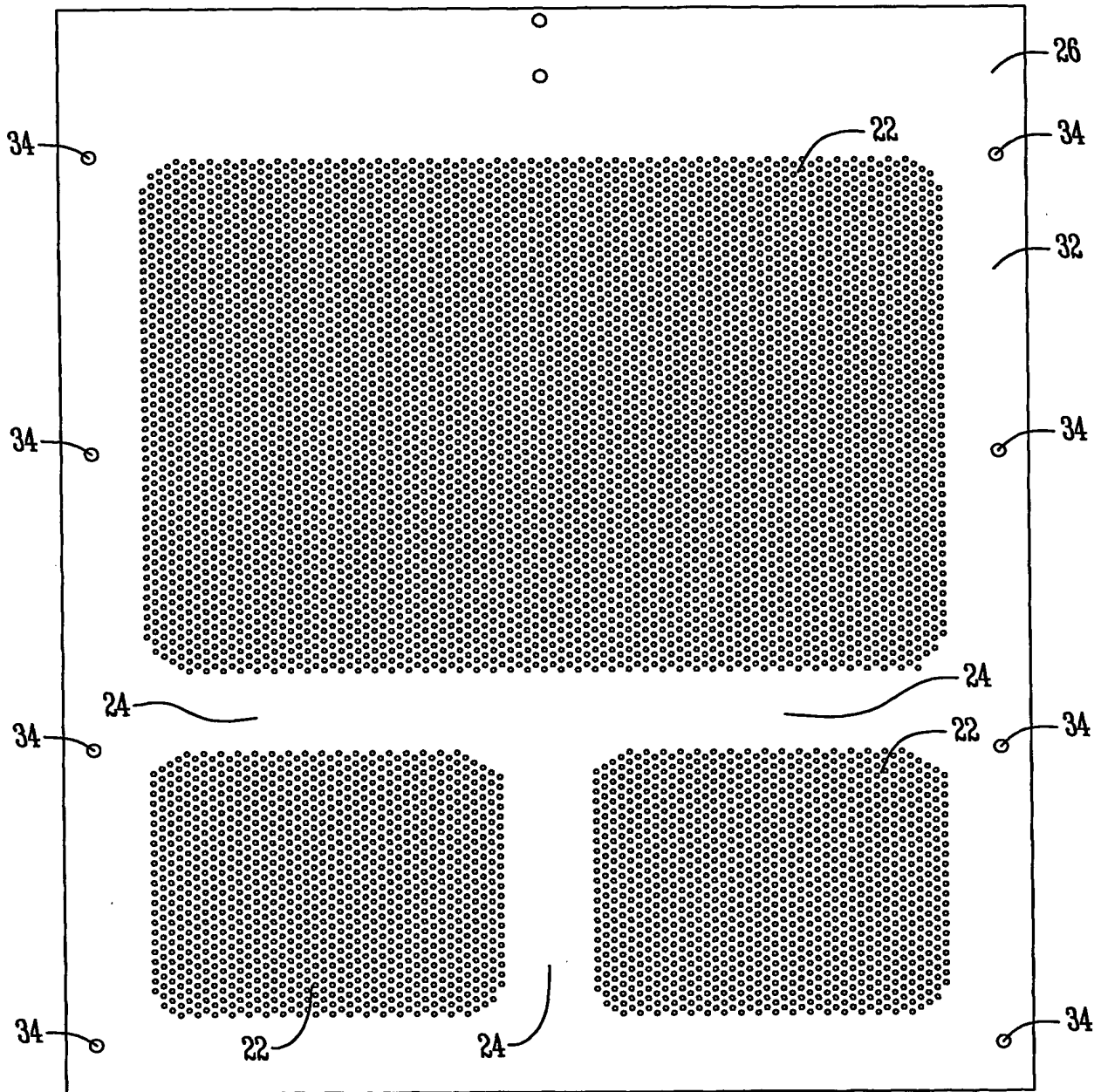
*Fig. 5*



*Fig. 6*



*Fig. 7*

*Fig. 8*

# INTERNATIONAL SEARCH REPORT

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**A. CLASSIFICATION OF SUBJECT MATTER**  
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According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B A61F A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 97 02942 A (AL KASSIM ADIL ;ALK ASSOCIATES (DK)) 30 January 1997 (1997-01-30) page 1 -page 2; figures 3A,3B ---	1-17
X	US 5 595 191 A (KIRK JOHN R) 21 January 1997 (1997-01-21)  figures 10,11 ---	1,2,4, 6-11,15, 16
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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International Application No

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